Appl. No.: 10/719,734 Patent Art Unit: 1616 1951300-00060

Reply to Office Action of March 23, 2009

## **Amendments to the Claims**:

This listing of claims will replace all prior versions, and listings, of claims in the application:

## **Listing of Claims:**

Claims 1-32 (Canceled)

- 33. (Currently amended) A method for delivering monomeric or dimeric insulin to a patient in need thereof, comprising administering to the patient a delivery formulation for the monomeric or dimeric insulin comprising an effective amount of insulin complexed with a diketopiperazine derivative, wherein the delivery formulation is prepared by complexing the insulin with microparticles of the diketopiperazine derivative by the steps of:
- a) providing pre-formed microparticles of <u>the</u> diketopiperazine <u>derivative</u> in a suspension comprising a solvent;
  - b) adding insulin to said suspension; and
  - c) removing solvent from said suspension;

wherein the diketopiperazine derivative has the formula 2,5-diketo-3,6-di(4-X-aminobutyl)piperazine, wherein X is selected from the group consisting of fumaryl, succinyl, maleyl, and glutaryl, and

wherein the microparticles release monomeric or dimeric insulin upon dissociation.

- 34. (Canceled)
- 35. (Previously presented) The method of claim 33 wherein X is fumaryl.
- 36. (Previously presented) The method of claim 33 wherein X is succinyl.
- 37. (Previously presented) The method of claim 33 wherein X is maleyl.
- 38. (Previously presented) The method of claim 33 wherein X is glutaryl.
- 39. (Previously presented) The method of claim 33 wherein the composition is in a dry powder form administered to the lungs via inhalation.

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40. (Previously presented) The method of claim 33 wherein the patient is a Type II diabetic.

- 41. (Currently amended) The method of claim 40 wherein the composition is administered concurrently with[[,]] or less than 20 minutes prior to[[,]] the patient eating a meal.
- 42. (Previously presented) The method of claim 33 wherein the composition is provided in one or more unit doses of insulin, each dose equivalent to about 6 IU of insulin.
- 43: (Previously presented) The method of claim 33 wherein said solvent is an aqueous solvent.
- 44. (Previously presented) The method of claim 33 wherein said solvent is removed by lyophilizing or freeze drying.